REFERENCE SHEET FOR INTERNATIONAL HUMAN SUBJECT RESEARCH

When conducting international research, principal investigators (PIs) and their research teams are responsible for maintaining the same ethical treatment of participants abroad as mandated under the Department of Health and Human Services 45 Code of Federal Regulations (CFR) 46, and US Food and Drug Administration 21 CFR 50, 56, as applicable. To ensure that research is conducted in an ethical manner, researchers are strongly urged to remain aware of the three ethical principles that serve as the basis for 45 CFR 46:

- **Respect for Persons:** Recognition of the personal dignity and autonomy of persons and the need for special protection for persons with diminished autonomy, such as children or prisoners.
- **Beneficence:** Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks.
- **Justice:** Fairness in distribution of the benefits and burdens of research.

Adhering to these three basic principles in other cultural or societal settings will often cause study procedures to be different from procedures of studies conducted within the United States. The information listed below should be included by PIs in Institutional Review Board (IRB) applications submitted for international human subject research.

1. The location(s) where the international research will be conducted
2. The specific research to be performed at Tufts and the specific research to be performed at foreign sites
3. The research setting/environment
4. The PI’s and co-investigators’ qualifications (e.g., training, experience) for performing research at the foreign locations indicated above
5. Cultural and/or societal norms that will be taken into account while conducting research; issues to consider include
   a. Local laws
   b. Age of majority
   c. Cultural sensitivities
   d. Perception of autonomy during the consent process (e.g., who is responsible for administering consent in that setting/culture and whether written consent is customary, etc.)
   e. Appropriate and/or beneficial means of compensation
6. Details about how contact will be initiated with participants in a sensitive and culturally acceptable manner
7. Information about the primary language at the study site(s); information and detail about the PI’s and the research team’s ability to speak, read, and write the language(s)
8. Details about the capacity in which translators will be involved (if they will be used)
9. Clarification whether the research has received IRB/ethics committee approval in the host country; a copy of the IRB/ethics committee approval letter, including translation if necessary, should accompany the submission to the Tufts IRB

For further assistance regarding international human subject research, please contact the Institutional Review Board:

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